

FEB - 7 2011

510(k) Summary

Submitted by: Kensey Nash Corporation
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Exton, PA 19341
484-713-2100

Contact Person: Lori Burns, MS, RAC
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Date Prepared: January 31, 2011
510(K) #: K103787

Device:
Trade Name: Medeor™ Matrix
Common Name: Surgical Mesh
Proposed Classification: 21 CFR 878.3300, Class II
Product Code: FTM

Predicate Device: Medeor™ Matrix (K091499) – Kensey Nash Corporation
KN ECM Surgical Patch (K094061) - Kensey Nash Corporation

Device Description:

The purpose of this submission is to add hydration with autologous bodily fluids to the labeling of the Medeor Matrix device. Medeor Matrix is a resorbable porcine-dermis-derived collagen surgical mesh intended for reinforcement of soft tissues where weakness exists. The device is supplied sterile in double-layer peel-open packages. The device is packaged either dry or hydrated with saline. The device can be hydrated with saline or autologous bodily fluids prior to implantation.

Intended Use:

Medeor™ Matrix is indicated for use in general surgical procedures for the reinforcement and repair of soft tissue where weakness exists including, but not limited to; defects of the thoracic wall, suture line reinforcement, and muscle flap reinforcement; hernia repair; soft tissue reconstructive procedures including plastic and reconstructive surgical applications, and for reinforcement of the soft tissues,

Kensey Nash

which are repaired by suture or suture anchors, including but not limited to, rotator cuff, patellar, Achilles, biceps, quadriceps and other tendons.

Medeor Matrix is not intended to replace normal body structure or provide the full mechanical strength to support tendon repair of the rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons. Sutures, used to repair the tear, and sutures or bone anchors used to attach the tissue to the bone, provide biomechanical strength for the tendon repair.

Medeor Matrix is intended for one time use.

Technological Characteristics:

There have been no changes to the design or manufacturing process of Medeor Matrix (K091499). Medeor Matrix is substantially equivalent to KN ECM Surgical Patch (K094061) with respect to its design, intended use and technological characteristics.

Performance Data:

The following biocompatibility tests were conducted on the finished device according to the requirements of ISO 10993-1:2003, Biological evaluation of medical devices – Part 1: Evaluation and testing: Cytotoxicity, Sensitization, Intracutaneous Reactivity, Systemic Toxicity, Sub-Chronic Toxicity, Genotoxicity, Implantation, Pyrogenicity and Hemolysis.

The manufacturing methods have been tested by an independent laboratory to assure appropriate levels of viral inactivation.

Mechanical test reports were completed for the following:

- Tensile Testing
- Suture Retention

Hydration testing was performed using various hydration fluids.

The device was evaluated in two *in vivo* studies; defects were repaired and evaluated in a sheep model and a rabbit study was performed to evaluate tissue reactions.

The Medeor Matrix surgical mesh passed the requirements of all tests.

Substantial Equivalence:

Performance Testing has confirmed that Medeor Matrix is substantially equivalent to the predicate devices with regard to materials, intended use, and technological characteristics, pursuant to section 510(k).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 16, 2014

Kensey Nash Corporation
Ms. Lori Burns
Manager, Regulatory Affairs
735 Pennsylvania Drive
Exton, Pennsylvania 19341

Re: K103787
Trade/Device Name: Medeor™ Matrix
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: Class II
Product Code: FTM, OXB, OXE, OXH, OWY
Dated: December 22, 2010
Received: December 27, 2010

Dear Ms. Burns:

This letter corrects our substantially equivalent letter of February 7, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Kensey Nash

Indications for Use Statement

510(k) Number: K103787

Device Name: Medeor™ Matrix

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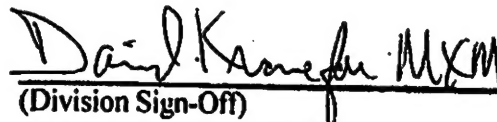
The device is intended for single use only.

Prescription Use X
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(Per 21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103787

1-800-524-1984

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